Dated: June 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12191 Filed 6–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0315]

Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.8 With Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule Version 1.0; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** on March 11, 2020. The document announced that FDA will begin supporting the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model version 1.8 (SDTM v1.8), and CDISC Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule version 1.0 (SENDIG–AR v1.0) on March 15, 2020, and that these new standards will be required in submissions to FDA effective March 15, 2022. The document omitted the 36-month implementation period for certain investigational new drugs applications (INDs) as required by the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' which is referenced in that document. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, email: *cderdatastandards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of March 11, 2020 (85 FR 14205), in FR Doc. 2020–04898, the following corrections are made:

1. On page 14205, in the second column, the first sentence of the **SUMMARY** is corrected to read: ''The Food and Drug Administration (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing that FDA will begin supporting the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model version 1.8 (SDTM v1.8), and CDISC Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule version 1.0 (SENDIG–AR v1.0) on March 15, 2020, and that these new standards will be required in submissions for studies that start after March 15, 2022 (for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs)), and in submissions for studies that start after March 15, 2023 (for certain investigational new drug applications (INDs)), that are submitted to CDER.''

2. On page 14206, in the first column, the last sentence of the document is corrected to read as follows: ''FDA will begin supporting SDTM v1.8 and SENDIG–AR v1.0 on March 15, 2020, and the use of these new standards will be required in Animal Rule [1] submissions for studies that start after March 15, 2022 (for NDAs, ANDAs, and BLAs), and in Animal Rule submissions for studies that start after March 15, 2023 (for certain INDs), that are submitted to CDER.''

Dated: June 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12198 Filed 6–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0362]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice for Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 12, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0139. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice for Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients—21 CFR Parts 210 and 211 and 21 U.S.C 351(a)(2)(B)

OMB Control Number 0910–0139—Extension

This information collection supports FDA regulations that govern the manufacture, processing, packing, or holding of finished pharmaceuticals, including medical gases, and active pharmaceutical ingredients (APIs). Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (CGMP) regulations. FDA is responsible for enforcing the FD&C Act as well as related statutes, including the Public Health Service Act. Congress enacted these laws to ensure that covered products meet applicable requirements regarding the safety, identity and strength, and the quality

[1] The Animal Rule refers to FDA's regulations for the approval of new drugs and biological products when human efficacy studies are not ethical or feasible (see 21 CFR 314.600–650 for drugs and 21 CFR 601.90–95 for biologics).

and purity characteristics they purport or are represented to possess, and are labeled with adequate warnings and instructions for use.

The pharmaceutical or drug quality-related regulations appear in several parts of Title 21 Code of Federal Regulations (CFR) (Food and Drugs), including sections in parts 1 through 99, 200 through 299, 300 through 499, 600 through 799, and 800 through 1,299. The regulations enable a common understanding of the regulatory process by describing requirements to be followed by drug manufacturers, applicants, and FDA. Under part 211 (21 CFR part 211; see 21 CFR 211.94(e)(1)), specific requirements for medical gas containers and closures are also found in the regulations. Finally, the information collection also supports regulations codified under parts 610 and 680 (21 CFR parts 610 and 680), which reference certain CGMP regulations in part 211 (see §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f)).

These regulations set forth information collection requirements that allow FDA to meet its public health protection responsibilities. Products that fail to comply with CGMP requirements may be rendered adulterated under section 501(a)(2)(B) of the FD&C Act. To demonstrate that their products comply with the requirements of section 501(a)(2)(B), API manufacturers must maintain CGMP records; therefore, we have counted them among respondents who incur burden for the information collection. In the table below, we have included an additional 1,260 respondents to reflect API manufacturers not included in our previous submission for renewal.

To assist respondents with the information collection requirements for medical gases, we developed a draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases.'' This guidance, when finalized will discuss our recommendations regarding compliance with applicable requirements found in the regulations as they apply to these products. The guidance is available for download from our internet site at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-medical-gases.* We believe the recommendations, if followed, will help respondents focus their information collection activities most efficiently with regard to demonstrating regulatory compliance.

In the **Federal Register** of March 3, 2021 (86 FR 12466), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received requesting clarification on FDA's basis in calculating its burden estimate. At the same time, the comment offered no formula or method upon which alternative figures might be derived. For details regarding all approved information collections currently in use by FDA, we invite readers to visit *https://www.reginfo.gov/public/jsp/PRA/praDashboard.myjsp.* With regard to this information collection specifically, our estimate of burden, as defined in 44 U.S.C. 3502(2), is based on our experience with routine inspections and informal communications with industry. Additionally, as noted in our 60-day notice, we account for burden that may be applicable to API and finished dosage manufacturers along with other respondents to the information collection. The estimate we provide reflects burden we attribute to activities associated with recordkeeping requirements found in applicable regulations, as well as recommendations that may be found in Agency guidance.[1] These activities include, among others, establishing and maintaining standard operating procedures; the need to consult outside experts; recommendations pertaining to documenting equipment cleaning and maintenance; and requirements and recommendations pertaining to master production records, control records, and distribution records.

We retain our estimate of the information collection burden, which is as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN—APIS, FINISHED PHARMACEUTICALS, AND MEDICAL GASES [1] [2]

Section 501(a)(2)(B) of the FD&C Act; Parts 210 and 211	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CGMP API Manufacturers	1,260	256	322,560	0.82 (49.2 minutes)	264,499
CGMP Finished Pharmaceuticals Manufacturers (excludes medical gases)	3,270	299	977,730	0.64 (38 minutes)	625,747
CGMP Medical Gases Manufacturers	2,284	280	639,520	0.62 (37 minutes)	396,502
Total			1,939,810		1,286,748

[1] There are no capital or operating and maintenance costs associated with the information collection.
[2] Records and burden per activity have been averaged and rounded.

Our estimated burden for the information collection reflects an overall decrease of 29,073 hours and 1,762 records annually for CGMP for finished pharmaceutical manufacturers, excluding those manufacturers of medical gases. Our estimated burden for the information collection also reflects an overall decrease of 486 hours and 1,574 records annually for medical gas manufacturers. Our inclusion of API manufacturers in this collection represents an addition of 264,499 hours and 322,560 records prepared.

Dated: June 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12214 Filed 6–9–21; 8:45 am]

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[1] See also, ''Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; Guidance for Industry'' (September 2016).